

Message

From: Wozniak, Chris [wozniak.chris@epa.gov]
Sent: 2/5/2016 8:46:09 PM
To: Evdokimov, [Evgenij.Evdokimov@fda.hhs.gov]
CC: Kough, John [Kough.John@epa.gov]
Subject: EPA review of draft EAs / FONSI
Attachments: Review of Draft EA and Investigational EA of Oxitec OX513A GE male-CAW-020416.docx; Oxitec draft EA review-CAW-012916.docx; Draft Oxitec Investigational EA-CAW-020216.docx; Preliminary FONSI-CAW-020416.docx; Antibiotics-HLB-citrus-Federal Register, Volume 81 Issue 17 (Wednesday, January 27, 2016).htm

Hi Evgenij,

Thanks for your patience on this one and the opportunity to comment! There was quite a bit to read as you know and the good news is that although we have some suggestions, I don't think there is anything in our comments or suggestions that is earth shattering. Hopefully some of our suggestions can be helpful to clarify in some places and head off any criticisms from those waiting for the opportunity. The documents are well written and a testament to all the work your team put into them!

I'm attaching copies of the Investigational draft EA, FDA draft EA and FONSI with comments and a couple of typos noted via track changes. Also, a separate Word document which lists the main items we think are worth attention. All of the comments in this last list are also found as comments / edits in the documents themselves, but thought it helpful to have them separated out as well.

Please let us know if there is anything that is not clear in our comments and perhaps we can chat next week as needed. Monday a lot of us are headed to a funeral so will not be around much, but after that I believe John and I are around the rest of the week.

One other item I will attach is an FR published recently in which the Citrus industry is seeking to treat large acreages of oranges / grapefruits in FL with three antibiotics, two of which are tetracyclines. While not directly affecting this EA or FONSI, it may complicate the analysis if Oxitec moves north in the state.

Have a nice weekend!

Chris

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